REMARKS/ARGUMENTS

Claims 50, 59, and 75 are amended by this response. No claims are canceled or added. Accordingly, following entry of these remarks, claims 50-77 will remain pending.

As an initial matter, Applicants acknowledge the Examiner's refusal to grant the pending claims the earlier priority date of the provisional patent application previously filed.

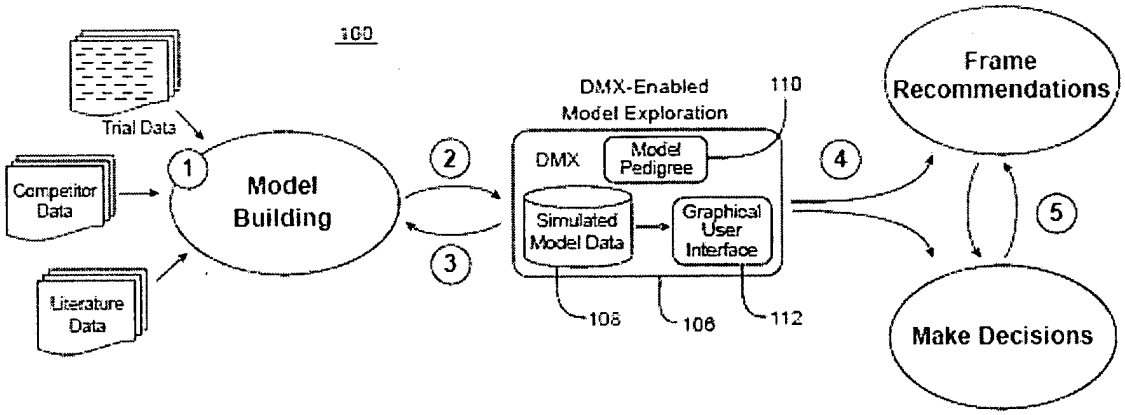
Turning now to address rejection of the pending claims, all claims stand rejected under 35 U.S.C. §112, for both purportedly failing to comply with the written description requirement (35 U.S.C. §112 ¶1), and for purported indefiniteness (35 U.S.C. §112 ¶2). These claim rejections are respectfully overcome as follows.

In the latest office action, the Examiner indicated a purported lack of written description for the phrase "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy in relation to a competitor compound". The Examiner asserted that this phrase constituted new matter.

However, the instant application does disclose the use of the DMX software to allow comparison of drug candidate behavior with that of competitors. Specifically, the Brief Summary of the Invention indicates that:

> [t]he software thus facilitates non-expert interaction with complex drug behavior models, streamlining the drug development process by providing decision-makers with a standardized framework for characterizing drug behavior across different candidates, across different models, and in relation to different competitors. (Emphasis added; ¶**[0025]**)

More particularly, in connection with step 4 of FIG. 1 (reproduced below), the instant application describes use of the DMX software to update a model:



> **[0053]** As model-building and decision making are interactive processes, new questions will arise, assumptions can change, new data can become available, or certain questions will become obsolete. In one or any of these evolving landscapes, the DMX software can facilitate updating the model and/or publication of a new simulation database for team exploration. (Emphasis added)

The application again emphasizes that such development of the model can in turn allow for comparison with the behavior of competing products:

> The DMX software enhances understanding of possible clinical potential and limitations of a drug relative to competitors at any point during development, and distributes that understanding across a project team and decision-makers. Users of the DMX software will be able to compare the probability distribution for different endpoints such as biomarker, efficacy, safety, and tolerability, for different treatment strategies, for different patient populations, and for different competing products. (Emphasis added; ¶**[0041]**)

Accordingly, independent claims 50 and 75 have now been amended to recite that a data subset presented by the model is used for updating the model to predict a drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound.

Based upon the support for this phrase in the application as filed, as demonstrated at least by the above-cited passages, it is respectfully asserted that the amended claims now satisfy the written description requirement. Continued maintenance of the claim rejections under 35 U.S.C. 112 ¶1 is accordingly improper, and the rejections should be withdrawn.

Turning now to address purported indefiniteness of the claims, certain claims have been amended to overcome the rejections. Specifically, claim 50 has been amended to change reference from the "raw data file" to simply "raw data", a term for which proper antecedent basis has been provided. Claim 50 has also been amended to change "presentation formats" to "presentation format", thereby providing proper antecedent basis for that term in the dependent claims. Claim 50 has further been amended to change reference from "a subset" to "a data subset", thereby providing proper antecedent basis for that term.

Claims 50 and 75 are also amended to clarify that "the model" introduced by the claim, is in fact the model the "model of clinical safety, tolerability, and efficacy of a drug candidate" that is referenced later in the claim. Finally, dependent claim 59 has been amended to change "output" to "outputs", in the manner suggested by the Examiner.

Regarding the remaining indefiniteness rejections, the Examiner is respectfully reminded that Applicants are afforded a wide latitude in their choice of claim terminology:

> A fundamental principle contained in 35 U.S.C. §112, ¶2 is that applicants are their own lexicographers. . . . Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim . . . . (Emphasis added; MPEP §2173.01)

Moreover, the MPEP directs the Examiner to:

> allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. (Emphasis original; MPEP §2173.02)

Here, the Examiner has alleged purported indefiniteness of the term "location". In particular, the Examiner has indicated uncertainty as to whether this term refers to a "physical location (a hospital or clinic) or a site of administration of a treatment (arm, leg) or some other 'location'" (Office Action Mailed September 21, 2007, page 5, lines 20-21).

Review of the instant application reveals no discussion of the term "location" in the context of a specific hospital/clinic or site of administration on the patient. However, careful review of the specification does reveal specific discussion of this term in connection with the location of data present in certain electronic data files.

For example, FIG. 10B (reproduced below) and the accompanying text explicitly reference the location of different elements in the DMX binary file:

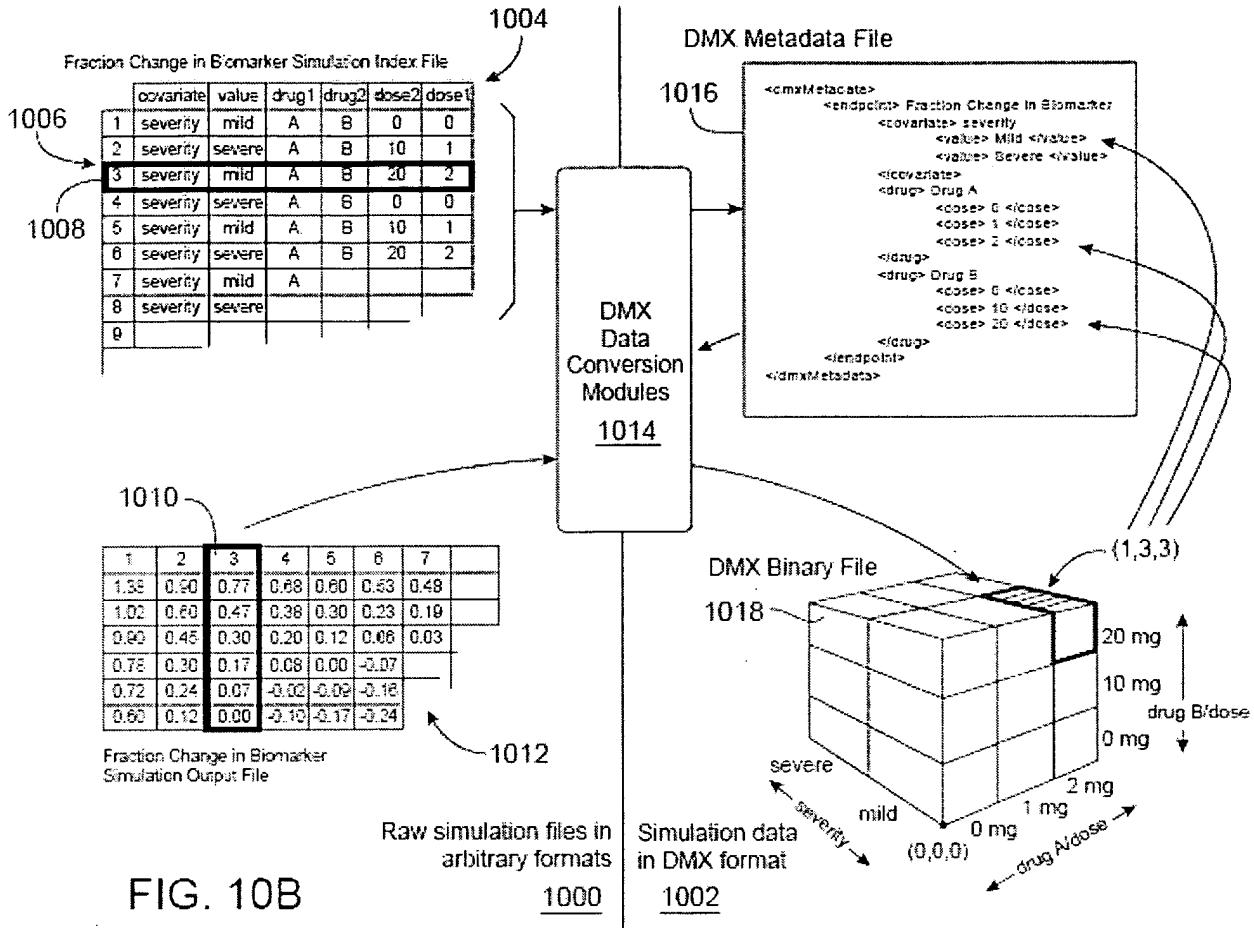


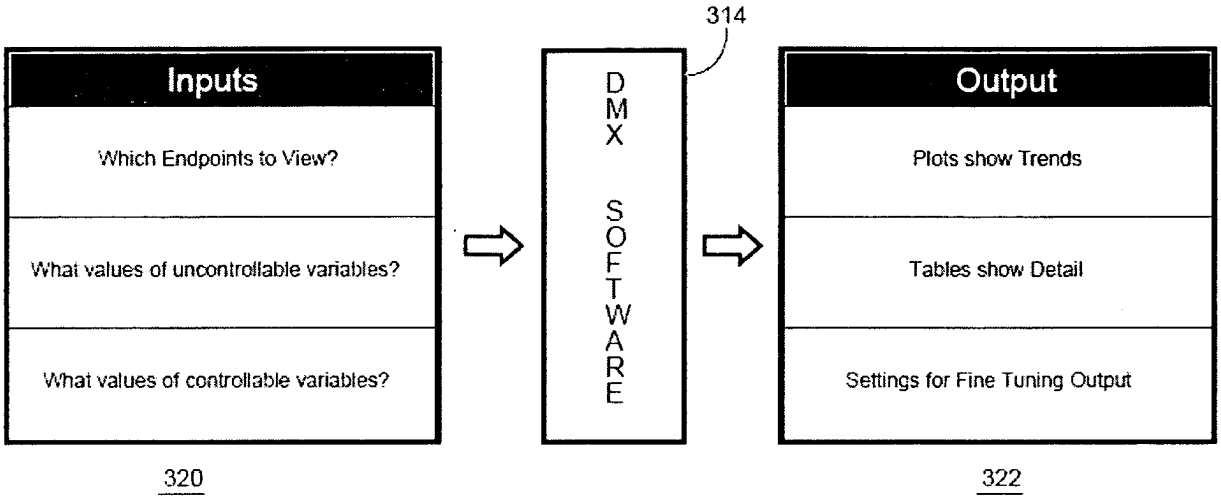
FIG. 10B

[0126] Review of the structure of DMX data files 1016 and 1018 reveals that taken together, they locate treatment types and corresponding simulated results in a manner which explicitly reflects the hierarchical structure of the original model. Specifically, in this conceptual example limited to 3 dimensions for the convenience of communication, binary file 1018 comprises a structure having X-, Y-, and Z- axes corresponding to each of the input variables. (Emphasis added)

Thus, the instant specification employs the term locate in the sense of the position of certain data in a particular electronic file. Such characterization is entirely consistent with the claim language, and certainly rises to the reasonable level of particularity and specificity called for by the MPEP. Accordingly, continued rejection of the claims based on this term is improper, and the claim rejection should be withdrawn.

In the latest office action the Examiner also concluded that determining a binary file "relevant" to a user selection, was indefinite. Again, however, the instant application provides ample disclosure regarding the meaning of this phrase.

For example, FIG. 5 (reproduced below) of the instant specification explicitly illustrates various types of output relevant to corresponding input from a user:



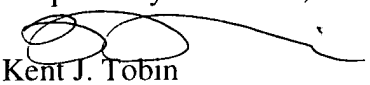
> Examples of inputs 320 to the DMX software 314 include but are not limited to 1) identification of endpoints to view, 2) values of uncontrollable variables, 3) values for controllable variables, and 4) modeling assumptions. Examples of outputs 322 from the DMX software 314 include but are not limited to 1) plots showing indicating trends in the data to be visualized by the software, 2) tables showing details of the data to be visualized by the software, and 3) settings for fine tuning data output by the software. (Emphasis added; ¶**[0134]**)

FIGS. 7A-N go on to provide more detail in the form of a number of screen shots illustrating various examples of output relevant to corresponding input from a user.

This description in the specification may not be as precise as the Examiner might desire. However, as amply evidenced above, the claim terms are discussed in the specification in connection at least with FIGS. 5 and 7A-N. Such disclosure certainly provides the reasonable degree of particularity and distinctness called for by the MPEP. Thus, continued maintenance of the indefiniteness claim rejections is improper, and the rejections should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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